



130-122

GP. 1207

PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of : Nancy Chang et al.
Serial No. : 06/659,339
Filed : October 10, 1984
For : CLONING AND EXPRESSION OF HTLV-III DNA

RECEIVED

MAY 17 1996

Assistant Commissioner for Patents
Washington, D.C. 20231

PETITION UNDER 37 C.F.R. §1.182

Sir:

Applicants are petitioning under 37 C.F.R. §1.182 to amend U.S.S.N. 06/659,339, now abandoned, to include a claim for benefit of co-pending application U.S.S.N. 06/643,306, filed August 22, 1984, and to add a reference to the pre-filing date deposit of a HTLV-III recombinant phage clone referred to in the specification of U.S.S.N. 06/659,339. A proposed amendment is submitted herewith together with a check in the amount of \$130.00 to cover the petition fee.

STATEMENT OF FACTS

1. U.S.S.N. 06/659,339 (the "'339 application") was filed on October 10, 1984. Drs. Nancy Chang, Flossie Wong-Staal

910 UJ 02/27/96 06659339
1 122 130.00 EN

Express Mail No.
EII 058 267 855 US

and Robert Gallo are the inventors¹. It was abandoned in favor of U.S.S.N. 06/693,866 ("the '866 application"); a continuation-in-part application filed on January 23, 1985. The '866 application is pending and is currently involved in Interference No. 102,822 (APJ Andrew Metz).

2. The '339 application is the grand parent application for U.S.S.N. 08/080,387 (the '387 application") filed on June 21, 1993. The '387 application is currently involved in Interference No. 103,659 (APJ Michael Sofocleus). Applicants are the Senior Party. Chiron Corporation is the real party in interest for the Junior Party.

3. U.S.S.N. 06/643,306, directed to Molecular Clones of the Genome of HTLV-III, was filed on August 22, 1984. This application describes the cloning of HTLV-III from an immortalized human T-cell line and the preparation of molecular clone λ BH-10. Drs. Flossie Wong-Staal, Robert C. Gallo, Beatrice Hahn and Mikulas Popovic are the inventors. The '339 application was co-pending

¹ As filed, the '339 application listed Dr. Nancy Chang as the sole inventor. On May 14, 1986, petitions to change the inventorship to add Dr. Robert Gallo and Dr. Flossie Wong-Staal were filed in the '339 application and in U.S.S.N. 06/693,866, the continuation in part application filed on January 23, 1985. Apparently, the '339 application was abandoned before the petition to change inventorship was acted upon. However, in Paper No. 13, issued November 27, 1987, the PTO examiner changed the inventorship of the '866 application to include Dr. Gallo and Wong-Staal. Pursuant to the Weil v. Fritz, 572 F.2d 856 (C.C.P.A. 1978) and In re Schmidt, 293 F.2d 274 (C.C.P.A. 1961) decisions, amendment of the '866 application was legally effective to change the inventorship of the '339 application. Thus, Drs. Chang, Gallo and Wong-Staal are the legal inventors of the '339 application.

with U.S.S.N. 06/643,306 and shares two common inventors, namely, Drs. Gallo and Wong-Staal.

4. Prior to the filing date of the '339 application, recombinant phage clones harboring HTLV-III DNA designated λ BH-5, λ BH-8 and λ BH-10 were deposited by Dr. Flossie Wong-Staal an inventor of the '339 application. On July 30, 1984 these clones were received by the American Type Culture Collection, 12301 Parklawn Drive, Rockville, MD, 20852, and accepted for deposit under ATCC accession numbers 40126, 40127 and 40125, respectively. The ATCC form recognizing the deposit and its acceptance is attached as Chang Documentary Exhibit 12. The deposit is in full compliance with PTO rules.

5. Clone λ BH-10 was specifically identified in the '339 application as set forth in detail in the attached proposed amendment.

6. On September 14, 1995, the United States District Court for the Northern District of California issued a decision in the action captioned Chiron Corporation v. Abbott Laboratories, Civil Action C-93-4380(MHP). The Applicants were not parties to the action. Abbott Laboratories is a licensee of the Applicants under the Chang applications. The decision is reported at 902 F. Supp. 1103 (N.D.Cal. 1995) (the "California Decision") and is attached as Chang Documentary Exhibit 1.

7. In the California Decision, the court, without the benefit of any expert testimony and on a record which the court characterized as "quite weak", found that the '339 application does

not enable one of ordinary skill to obtain or make the starting material, i.e., the HTLV-III clones (the "starting material finding"). Chang Documentary Exhibit 1, 902 F. Supp at 1126.

8. In the California Decision, the Court noted that Chiron had asserted that the '339 application did not indicate that the inventors possessed a means for making a recombinant clone encoding the env region of HTLV-III. The court made no finding on this issue (the "written description issue"). Chang Documentary Exhibit 1, 902 F. Supp at 1128-1129.

9. In the California Decision, the court again, on a very limited record, found that the '339 application fails to set forth the best mode based upon the absence of an enabling disclosure regarding the starting material, i.e., HTLV-III clones (the "best mode finding"). Chang Documentary Exhibit 1, 902 F. Supp. at 1129.

REASONS FOR GRANTING PETITION

The petition to enter these amendments in the '339 application should be granted because the amendments are in accordance with PTO rules and practice and Federal Circuit precedent and may facilitate resolution of issues in the interferences.

The amendment seeking to add the specific reference to the '306 application is appropriate under 35 U.S.C. § 120. The '306 application was filed by two inventors common to this application and was co-pending. The '306 application describes the

cloning of HTLV-III and the preparation of a molecular clone of HTLV-III used in the '339 application. The amendment seeks to add a specific reference to the earlier filed '306 application. Since the '339 application is abandoned, a petition to the Commissioner is appropriate. Under the authority of Sampson v. Commissioner of Patents, 195 U.S.P.Q. 136 (D.C.D.C., 1976), entry of the amendment to the '339 application is appropriate.

The amendment to the application adding the reference to the deposit of the HTLV-III clone at the ATCC is also proper under In Re Lundak, 773 F.2d 1216 (Fed. Cir. 1985). As the Court noted:

Constructive reduction to practice does not turn on the question of who has possession of a sample, and thus it does not turn on the inclusion or absence, in the specification as filed of the name and address of who will have possession of the sample on grant of the patent.

* * *

We conclude that the insertion of depository data after filing is not new matter under 35 U.S.C. § 132.

773 F.2d at 1223. The Court of Appeals further noted:

[T]he function of section 112 in ensuring *complete public disclosure* is only violated if the *disclosure* is not complete at the time it is made public i.e. at the issue date.

773 F.2d at 1223 (citations omitted).

The entry of these amendments is warranted in equity to address the starting material finding, the written description issue and the best mode finding in the California Decision, which

Chiron will undoubtedly raise in the interference. The California findings are erroneous, particularly in light of the deposit and resulting availability of the starting material, which is specifically identified in the '339 application, and the description in the '306 application of the molecular cloning of the HTLV-III starting material. The entry of the amendments are fully warranted under controlling law. Accordingly, entry of the proposed amendment is fully justified.

CONCLUSION

Applicants respectfully request that the petition be granted and that the amendment to the '339 application be entered to protect Applicants' patent rights.

AUTHORIZATION

The Assistant Commissioner is hereby authorized to charge any additional fees which may be required in this application,

including a petition fee, to Deposit Account No. 13-4500, Order No.
1436-4094.

Respectfully submitted,

MORGAN & FINNEGAN, L.L.P.

By:



Eugene Moroz
Reg. No. 25,237

Of Counsel:

William S. Feiler
M. Caragh Noone
Dorothy R. Auth
MORGAN & FINNEGAN, L.L.P.
345 Park Avenue
New York, New York 10154
(212) 758-4800
(212) 751-6849 (FAX)

CERTIFICATE OF MAILING

I hereby certify that this correspondence is being deposited with the United States Postal Service as Express Mail in an envelope addressed to: the Assistant Commissioner for Patents, Washington, D.C., 20231, on February 20, 1996.

Dated: February 20, 1996

By:


Eugene Moroz



American Type Culture Collection

12301 Parklawn Drive • Rockville, MD 20852 USA • Telephone: (301)881-2600 Telex: 898-055 ATCCNORTH

BUDAPEST TREATY ON THE INTERNATIONAL RECOGNITION OF THE DEPOSIT OF MICROORGANISMS FOR THE PURPOSES OF PATENT PROCEDURE

INTERNATIONAL FORM

RECEIPT IN THE CASE OF AN ORIGINAL DEPOSIT ISSUED PURSUANT TO RULE 7.3 AND VIABILITY STATEMENT ISSUED PURSUANT TO RULE 10.2

To: (Name and Address of Depositor or Attorney)

National Institutes of Health, National Cancer Institute
Building 37, Room 6A17
9000 Rockville Pike
Rockville, Maryland 20205
Attention: Dr. Flossie Wong-Staal

Deposited on Behalf of: National Institute of Health, National Cancer Institute

Identification Reference by Depositor:

ATCC Designation

λ EH-10 recombinant phage clone of HTLV-III in λ g & Wes λ B
λ EH-5 recombinant phage clone of HTLV-III in λ g & Wes λ B
λ EH-8 recombinant phage clone of HTLV-III in λ g & Wes λ B

40125
40126
40127

The deposits were accompanied by: ___ a scientific description ___ a proposed taxonomic description indicated above.

The deposits were received July 30, 1984 by this International Depository Authority and have been accepted.

AT YOUR REQUEST:

☐ We will inform you of requests for the strains for 30 years.
☒ We will not inform you of requests for the strains.
☐ The strains are available to the scientific public upon request as of

The strains will be made available if a patent office signatory to the Budapest Treaty certifies one's right to receive, or if a U.S. Patent is issued citing the strains.

If the cultures should die or be destroyed during the effective term of the deposit, it shall be your responsibility to replace them with living cultures of the same:

The strains will be maintained for a period of at least 30 years after the date of deposit, and for a period of at least five years after the most recent request for a sample. The United States and many other countries are signatory to the Budapest Treaty.

The viability of the cultures cited above were tested March 4, 1987. On that date, the cultures were viable.

International Depository Authority: American Type Culture Collection, Rockville, Md. 20852 USA

Signature of person having authority to represent ATCC: Bobbie A. Brandon
(Mrs.) Bobbie A. Brandon, Head, ATCC Patent Depository

Date: March 6, 1987
cc: James A. Oliff, Esq.

Form ATCC 4-79

P-3

NOV 22 95 10:33AM ATCC

Documentary Exhibit 12
CHANG ET AL.
Interference No. 103,659